

Sub. 14, 1997

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510(k) Summary

Submitter: Sahar Technologies, Inc.

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Date prepared: November 12, 1996

Trade name: SofTouch

Common name: Laser Accessory

Classification name: Class II 

Substantial equivalence claimed to:

1. Clinicon Corporation SureScan 510(k) number - K962242
2. Lasersonics Parascan - 510(k) number - K955734

Description:

Adding the SofTouch to any laser will convert the system into a sophisticated easy to use aesthetic surgery tool that can perform the widest range of cosmetic procedures. SofTouch may be used for a variety of soft tissue ablation procedures, including aesthetic laser surgery where layer by layer of micro-ablation is required. SofTouch introduces an extra dimension of control for precise tissue removal using lower power than previously thought possible. The SofTouch aiming beam mode visually displays the area about to be treated on the tissue. While watching the aiming beam, the physician can change the shapes and sizes he selects to use. The aiming beam outline will change in a concurrently to continuously display the area that is about to be treated.

Filling the area is done using a precise computer control motion that deflects the laser beam on the tissue to ensure maximum accuracy and homogeneity. Coordinating the laser

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emission is done by the SofTouch while leaving the physician in full control of laser emission at all times.

Intended use:

~~Soft tissue treatments and in particular skin treatments require~~ a device that can cover large and variable areas in a safe and homogeneous way. The SofTouch provides the ability to cover large and small areas of soft tissue while having perfect control of the emission placement and the emission reproducibility. The ability of the physician to identify the area to be treated by watching the aiming beam, while controlling the shape and the size that best fits the treated area will enhance the precision and safety of the treatment. The timing of the emission placement on the tissue is done by the SofTouch hardware and software to avoid errors and to increase precision and homogeneity. SofTouch is a hand held device that is flexible enough to allow the physician the freedom to choose the area of treatment without being restricted by the system.

Summary of technological characteristics:

Technologically, the SofTouch Scanning System offers all of the features and functionality of the Clinicon Surescan and Lasersonic's Parascan, which both offer features and functionality in excess of the Coherent CPG. The SofTouch offers greater flexibility than the others in terms of different wavelength specific applications.

Microprocessor controlled scanning systems in general bring improved safety to the laser marketplace due to the increased control, precise placement, and homogeneous application of laser energy.

Because of the normally tedious nature of applying single spot laser energy over large areas, the SofTouch improves safety by decreasing fatigue experienced by the physician during a procedure. The high bandwidth design of the SofTouch system offers scanner capabilities previously unavailable in any application other than CO2 soft tissue, extending the safety and effectiveness improvements to a broader range of procedures.

The improved performance of the SofTouch device allows for better fluence at lower power levels, which is also a net increase in safety.

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